Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Military Operational Medicine Research Program/Joint Program Committee-5

Alcohol and Substance Abuse Research Program

Consortium Award

Funding Opportunity Number: W81XWH-14-ASARP-CA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-application Deadline:** 5:00 p.m. Eastern time (ET), February 26, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, March 5, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, March 10, 2015
- **Peer Review:** April 2015
- **Programmatic Review:** May 2015

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. Funding Opportunity Description

A. Program Description

Applications to the Fiscal Year 2014 (FY14) Alcohol and Substance Abuse Research Program (ASARP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation appropriation. The Department of Defense (DoD) Congressionally Directed Medical Research Programs (CDMRP) operates in partnership with the Joint Program Committee 5/Military Operational Medicine Research Program (JPC-5/MOMRP) to provide oversight and execution management for the ASARP.

The JPC-5 consists of DoD and non-DoD medical and military technical experts relevant to the MOMRP area. MOMRP oversees an extensive portfolio of research aimed at developing effective countermeasures against stressors to maximize health, performance, and well-being throughout the deployment cycle. MOMRP psychological health and resilience research is focused on prevention, treatment, and recovery of Service Members' and Families' behavioral health which is critical to force health and readiness.

The goal of the ASARP is to identify and develop new medications to improve treatment outcomes for alcohol and substance use disorders (ASUD), especially as related to traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD). The program encourages the use of collaborative, multidisciplinary approaches to accelerate the translation of basic research into clinical trial studies.

The program's approach is to organize multidisciplinary, team-based translational research efforts to:

1. Identify promising compounds;
2. Conduct proof-of-principle basic research to determine which compounds are most appropriate for human research trials;
3. Conduct human proof-of-principle trials with promising compounds**.** This approach should accelerate the translation of contemporary basic science knowledge into enhanced clinical pharmacological treatment protocols for ASUD, including a regulatory strategy for U.S. Food and Drug Administration (FDA) compliance.

B. Award Information

The ASARP Consortium Award will support the establishment of a Consortium that includes collaborations of multiple organizations and individuals for the purpose of identifying promising compounds with the goal of translating basic science knowledge into enhanced clinical pharmacological treatment protocols for ASUD. The Consortium will ultimately consist of a single Management Core as well as basic research and clinical trial sites. The participants will be jointly responsible for prioritizing, proposing, conducting and analyzing proof-of-principle basic research and proof-of-principle human clinical trials and developing a

roadmap to translate promising basic science knowledge into enhanced clinical pharmacological treatment protocols for ASUD, including a regulatory strategy for FDA compliance.

The Management Core must apply to this Program Announcement/Funding Opportunity through a single application, and may also serve as a future research and/or trial site. The award resulting from this Program Announcement/Funding Opportunity will be issued as a cooperative agreement between the recipient (Management Core) and the Government. The Government will have substantial involvement in the Consortium through a Government Steering Committee (GSC) and USMRMC staff interactions with the Consortium. Award funds will be used to support the Management Core's efforts as well as Consortium-associated studies at the to-be-determined basic research and clinical trial sites. The Management Core will provide management and funding through the appropriate subaward or other instruments for the basic research and clinical trial sites.

Award selection will depend upon evaluation of the organization of the Consortium, available capabilities, the proposed research strategy for basic research and clinical trials to be implemented, and the feasibility of the collective group to accomplish the overall award objectives. Applications should highlight the ability of the proposed Management Core to establish research collaborations. During the performance period of the award, the Management Core and all basic research and clinical trial sites will be responsible for working collaboratively to identify new basic research projects and clinical trials for implementation by the Consortium. **Clinical trials that include military and Veteran populations are encouraged.**

The ASARP plans to allocate FY14-FY16 funding, if appropriated, in support of the ASARP Consortium. The ASARP Consortium will be funded initially with allocations from the FY14 ASARP Congressional appropriation. Two additional options , to be included in the application, may be funded, subject to GSC review, approval of the Grants Officer, and receipt of future congressional appropriations. There also exists the possibility of further expanding the ASARP Consortium, contingent on receipt of sufficient future Congressional appropriations. Therefore, a supplemental research plan that is within the scope of work of the ASARP Consortium may be requested during the period of performance of the award to allow for expansion (i.e., additional basic research and/or clinical trials and/or more research sites) of the Consortium should additional funds be allocated by the ASARP. The ASARP concept for the ASARP Consortium is that following the award period of 5 years, the Consortium will be an ongoing, self-sustaining entity.

C. Consortium Structure

The Consortium framework will consist of a Management Core that will provide leadership, oversight, and infrastructure support to competitively-selected basic research and clinical trial sites.

1. Management Core

The Management Core Principal Investigator (PI) must be located at the Management Core and will serve as the Director of the Consortium, Chair of the Consortium Steering Committee (CSC), and the primary liaison with the Grants Officer Representative (GOR). The Management Core PI must have strong collaborative leadership experience and must demonstrate a broad understanding of research, including knowledge of the current state of ASUD research with respect to the military context.

The Consortium shall consist of one central Management Core that will be responsible for the planning, prioritizing, and soliciting proposals, and providing oversight and coordination for future proof-of-principle basic research projects and proof-of-principle human clinical trials supported by the Consortium. The Management Core will provide the administrative, protocol development and review, regulatory, statistical, resource, and data management/storage functions necessary to facilitate rapid development and accelerate translation that would perhaps not otherwise be feasible without the Consortium approach. The Management Core must contain multidisciplinary expertise and extensive experience in support of ASUD research. The Management Core will manage the regulatory strategy for FDA compliance leading to potential product development and licensing.

The application should identify and describe core facilities and functions that the Management Core will provide to the Consortium participants (i.e., data management, statistical analysis, scientific communication, etc.).

The Management Core will be responsible for establishing procedures for releasing a competitive call for basic research and clinical trial proposals and is responsible for coordinating all aspects of proposal receipt and review including external independent scientific peer review.

2. Basic Research and Clinical Trial Sites

The Consortium shall present a plan for incorporating basic research and clinical trial sites necessary to effectively support the Consortium goals. The plan should include criteria that will be used to evaluate and select studies and sites. Criteria should require all sites to have experience and multidisciplinary expertise in supporting ASUD research. It is preferred that some of the sites have experience working with military and Veteran populations. The selection of sites must be based on factors including:

- Lead site PIs' commitment to and experience in ASUD research. It is expected that there be a succession plan provided to account for any unforeseen change in the lead site PIs.
- Evidence of multidisciplinary clinical and/or laboratory expertise within the institution that could serve as the basis for the development of clinical protocols by the Consortium.
- Demonstration of adequate resources for coordinating with the Management Core and other sites.

- Demonstration of adequate resources and expertise for data management, and maintenance of data security/confidentiality.
- Evidence of institutional commitment to using facilities and resources in the conduct of Consortium studies, as required.
- Documentation of procedures to resolve intellectual and material property issues.
- Demonstration of adequate resources and expertise in ASUD patient recruitment and processing, including specimen collection.
- Ability to enroll military and Veteran participants into Consortium-sponsored studies.
- Ability to support common data element requirements and share data with the Management Core

Additional competencies of proposed sites may be identified and justified as being essential to the success of the Consortium.

D. Summary of Responsibilities

1. Responsibilities of all Consortium Participants:

All Consortium participants must agree to adhere to the Consortium procedures established by the Management Core. The process shall be codified in a Manual of Operations or Standing Operating Procedures (SOP) document, which will be provided to the GSC upon request. The SOP will include a plan for the CSC composition and responsibilities. The CSC plan responsibilities will include determining appropriate overall minimum and maximum accrual metrics for clinical trial sites per trial as part of the Consortium SOP. The Consortium SOP should also contain a plan to address underperforming sites, and a succession plan for any unforeseen change in the lead PI.

2. Consortium Management Core will:

- Be led by the Management Core PI, who will serve as the Director of the Consortium, Chair of the CSC, and the primary liaison with the GOR/Science Officer (SO) and the GSC.
- Ensure that the Consortium adheres to the planned timeline and milestones for overall study execution.
- Manage the Consortium organizational structure.
- Manage Consortium-developed procedures for external independent scientific review, prioritization, and implementation of studies proposed by or through Consortium members.
- Manage procedures to ensure that all sites maintain compliance with local Institutional Review Boards (IRBs) and the USAMRMC Human Research Protection Office (HRPO) for the proper conduct of clinical studies and the protection of human subjects; or to the Office of Research Protections (ORP) if there is a potential for animal studies.
- Provide a Consortium Clinical Research Manager who will oversee and support the efforts of the Research Coordinators at each of the basic research and clinical trial sites.

The Consortium Clinical Research Manager will be responsible for coordinating and facilitating clinical protocol approval, patient accrual, and study activities across all sites. For individual clinical studies, the Management Core should ensure the maintenance of overall patient accrual per year, appropriate for the target population.

- Ensure that all investigators are FDA registered to use Investigational New Drugs (INDs); and manage procedures for ensuring compliance with FDA requirements for investigational agents, devices, and procedures.
- Manage a communications plan and a real-time communications system between the Management Core and basic research and clinical trial sites.
- Manage standardization and, when appropriate, centralized review of imaging, histopathology, neuropsychological, and other data through committees and scientific core facilities.
- Manage Consortium-developed quality assurance and quality control mechanisms for study monitoring, including, but not limited to:
    - On-site monitoring program (to include safety).
    - Management plan for the handling, distribution, and banking of specimens and imaging products generated from Consortium studies.
    - Registration, tracking, and reporting of participant accrual.
    - Timely medical review, rapid reporting and communication of adverse events as well as establishment of a safety committee to provide timely analysis of adverse events.
    - Interim evaluation and consideration of measures of outcome.
- Manage Consortium-developed comprehensive data collection and data management systems that address the needs of all basic research and clinical trial sites in terms of access to data, data security, and data integrity measures.
- Implement statistical execution plans/support for all Consortium clinical studies.
- Manage costs to support the basic research and clinical trial sites, including provision of personnel, equipment, and materials required to conduct approved clinical studies.
- Track financial disbursements and cost-schedule performance of the overall Consortium as well as the Consortium supported studies.
- Manage Consortium-related intellectual and material property issues among organizations participating in the Consortium.
- Manage Consortium-developed procedures for the timely publication of major findings and other public dissemination of data.
- Coordinate the preparation of briefings to the GSC and USAMRMC in-person, by teleconference, and/or video teleconference.
- Manage the regulatory strategy for FDA compliance leading to potential product development and licensing.

- Develop, organize, and submit quarterly written progress reports, annual reports, and a final written comprehensive report to the GSC and USAMRMC. These reports must outline accrual and retention statistics, any problems with study execution, and actions to disseminate study results.

3. Basic Research and Clinical Trial Sites (to-be-selected after award) will:

- Designate a lead site PI and develop a succession plan upon request in case of departure of the site PI; the site PI must agree to adhere to the Consortium SOP and participate fully in the CSC.
- Identify potential studies and develop proposals in accordance with the Consortium SOP for consideration for funding by the ASARP during the performance period of the award.
- Collaborate with other Consortium basic research and clinical trial sites.
- In accordance with Consortium-developed guidelines, maintain a minimum combined participant accrual across all Consortium-associated clinical studies.
- As applicable, provide a Clinical Research Coordinator who will interact with the Clinical Research Coordinators of other basic research and clinical trial sites and the Consortium Clinical Research Manager at the Management Core to expedite and guide clinical protocols through regulatory approval processes, and to coordinate patient accrual and study activities across sites.
- Implement the Consortium's core data collection methodology and strategies.
- Comply with Consortium-developed quality assurance and quality control procedures, as appropriate, including:
    - Participation in an on-site monitoring program to be managed by the Management Core.
    - Implementation of the Consortium-developed management plan for acquisition and aggregation of protocol-specified specimens, biological fluids, and relevant data to the appropriate laboratories for testing and/or storage.
    - Submission of appropriate data and materials to allow for verification and review of protocol-related procedures (e.g., pathology, imaging techniques, surgical methods, and therapeutic use).
- Implement procedures established by the Management Core for ensuring compliance with FDA requirements for investigational agents, as appropriate.
- Implement procedures established by the Management Core to meet local IRB and USAMRMC HRPO requirements for the conduct of clinical trials and the protection of human subjects.
- Serve as a resource or core for the conduct of protocol-specified laboratory projects (including correlative studies), as appropriate.
- Participate in Consortium-developed procedures for the timely publication of major findings.

- Participate in Consortium-developed procedures for resolving intellectual and material property issues among organizations participating in the Consortium.
- Participate in the preparation of written and oral briefings to the GSC and USAMRMC staff at one-day meetings to be held in the Baltimore, MD/Washington DC area.
- Assist with the preparation of quarterly written progress reports, annual reports, and a final comprehensive report.
- Prepare for a site visit audit, if requested by the GSC.

E. Strategic Research Plan

Applicants must provide a strategic research plan that includes the Consortium aims and objectives. The plan should include the scientific rationale behind the Consortium approach to achieve the aims and objectives. The plan should include a description of the types of studies that will be solicited and how these will contribute toward accelerating the delivery of effective treatments for ASUD. The plan should project the number, types, and scope of basic research projects and clinical studies the Consortium expects to execute during the performance period of the award. The strategic plan should outline a feasible timeline that aligns milestones and deliverables with the Consortium aims and objectives. It is expected that that within the first year of award, a solicitation will be released and at least two studies will be selected and awarded.

F. Oversight of the Consortium

1. Government Steering Committee

The JPC-5/MOMRP will appoint Federal employees members to a GSC. The role of the GSC will be to provide oversight and advise the CSC on ASARP progress and activities, and to conduct programmatic review of CSC recommended study proposals. The GSC will be responsible for recommending studies to be executed and may recommend future studies and/or focus areas to the Consortium. The GSC will advise the CSC on the regulatory strategy for FDA compliance leading to potential product development and licensing. The Consortium must present written reports and oral briefings to the GSC and USAMRMC staff. Based on these reports and presentations, the GSC will advise the GOR. USAMRMC staff will evaluate progress, provide feedback, and invoke modifications as needed to facilitate the success of the Consortium. The USAMRAA Grants Officer will issue final approvals for the Statement of Work and budget, and release of funds for initiation of studies.

2. Consortium Steering Committee

The Management Core will appoint members to the CSC, which will be comprised of the Management Core PI, the research site PIs and additional ad hoc subject matter expert representatives (as needed). The CSC will be responsible for identifying, prioritizing, and guiding proof-of-principle basic research studies to determine which compounds are most appropriate for human research trials, as well as proof-of-principle clinical trials to test promising compounds. All studies considered for funding will undergo an external independent scientific review, and upon further review by the CSC which will provide an

Order of Merit List of studies recommended for funding to the GSC. In addition to basic research projects and clinical trials as part of the ASARP, the Consortium members are encouraged to submit additional applications to the CSC if additional funding opportunities are available. Pursuit of funding by the Consortium from additional sources including industry, private sector, and other Federal organizations is encouraged. The CSC will develop the regulatory strategy for FDA compliance leading to potential product development and licensing. The Management Core staff will be responsible for facilitating and coordinating these processes. The CSC, through the Management Core PI, will be expected to maintain monthly or more frequent contact with a Government appointed GOR/SO.

G. Use of Human Subjects and Human Anatomical Substances

All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC ORP, HRPO, in addition to the local IRB of record. Local IRB approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.

H. Use of Active Duty Military and Veteran Populations or Resources

If the proposed research involves access to military and/or Department of Veterans Affairs (VA) population(s) and/or resource(s), the PI is responsible for establishing and demonstrating access. If possible, access to target military and/or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the appropriate approval authority, should be included for studies involving military Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. Use Attachment 2 to provide this documentation (see Section II.C., Application Submission Content and Form, Supporting Documentation).

I. Data Elements and Sharing:

JPC-5/MOMRP strongly encourages the incorporation of measures from the Core and Specialty collections, which are available in the Substance Abuse and Addiction and Mental Health Research Collection of the PhenX Toolkit https://www.phenxtoolkit.org/index.php into all studies involving human subjects.

The DoD requires that awardees make TBI data generated via this award mechanism available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System on a quarterly basis. The FITBIR Informatics system is a free resource to the research community designed to accelerate comparative effectiveness research on brain injury diagnosis and treatment. Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others doing similar research. While there is no direct charge to users of the FITBIR informatics system, a

project estimation tool (https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp) is available to help estimate costs and manpower needs that may be associated with data submission. To contribute to FITBIR, researchers should contact the FITBIR Operations Center ahead of time to arrange for data entry support and to ensure all data have been made compatible with the system. FITBIR guidance and policies, as well as the considerable advantages of FITBIR use to the researcher, are detailed at FITBIR: Federal Interagency Traumatic Brain Injury Research Informatics System http://fitbir.nih.gov/.

FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's Global Unique Identifier system facilitates repeated and multi-user access to data without the need to personally identify data sources. FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards.

Data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI Common Data Elements (CDEs) or entered into the FITBIR data dictionary as new, unique data elements. For the most current version of the NINDS TBI CDEs, go to http://www.commondataelements.ninds.nih.gov. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR informatics system. If the proposed research data cannot be entered in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for use. Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI.

JPC-5/MOMRP and the CDMRP intend that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section L.

J. Eligibility Information

- The Management Core PI must be an independent investigator at or above the level of Associate Professor (or equivalent) at an eligible organization.
- Cost sharing/matching is not an eligibility requirement
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

K. Funding

A single award to the Management Core applicant will be made to support the ASARP Consortium. The Management Core will provide funding support for the selected basic research and clinical trial sites as openly competed sub-awards or other appropriate contracting instrument. The Management Core will clearly delineate Consortium infrastructure costs and research costs. Budget out-years should be projected based on the proposed costs of the anticipated studies, with appropriate escalation factors included. Following award, a budget for each study will be negotiated once study selections are made.

- The maximum period of performance is **5** years.
- The maximum allowable total costs (direct and indirect) for the entire period of performance are **$10.8M** of which only **$3.6M** is currently available.
    - **Base Funding**: The applicant may request up to $3.6M in total costs for the period of performance (up to 5 years) to cover Management Core costs and Consortium activities, as well as costs for research projects and clinical trials. This will be funded using allocations from the FY14 ASARP Congressional appropriation. The budget should include a separate line item for the base funded research project and clinical trial costs. The total for this base funding must not exceed $3.6M in total costs.
    - **Optional Funding**: In addition to the base funding above, the applicant may request two options of up to $3.6M in total costs each, to fund additional basic research projects, clinical trials, associated Management Core costs, and Consortium activities. Funding for these options (if exercised) is contingent upon receipt of future Congressional appropriations. The cooperative agreement will contain options with corresponding budgets. The overall Consortium budget should contain separate items for Management Core and research costs for studies to be funded with the option funding.
    - No project shall be initiated until the Statement of Work (SOW) and budget are approved for each project selected for funding. None of the funds for research projects may be utilized in other budget categories except with the express written approval of the Grants Officer.
- Exercising the options for additional funding (if available) will be dependent on the Consortium presenting written reports and oral briefings to the GSC and USAMRMC that demonstrate progress and alignment of the Consortium with the goals of the ASARP. Exercise of an option is at the unilateral discretion of the Government.
- Costs for a clinical trial study must be included within a single funding option and cannot depend on future appropriations.
- The Management Core is expected to provide a mechanism to transfer resources such as supplies and support necessary to the military treatment facilities, DoD laboratories, or DoD activities embedded within a civilian medical center to support their participation in Consortium studies.

- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable total costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions***.

For this award mechanism, direct costs:

Must be requested for:

- Travel costs for the Management Core PI and Study Site PIs to attend In-Progress Review and GSC meetings at a Government location (to be determined). For planning purposes, it should be assumed that the meetings will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary support.
- Implementation of Consortium-developed standardization plan, data management program, real-time communications system, and administration plans for the Consortium.
- Support of Consortium-related meetings, teleconferences, and travel among participating investigators.
- Costs associated with the external scientific peer review of proposed studies.
- Purchase of computers, specialized software, and specialized software licenses for research sites when required to fulfill Management Core-specific tasks.
- Purchase of minor equipment necessary for specimen collection and data storage and transfer.
- Costs associated with using Consortium core facilities.
- Costs associated with conducting the IRB review of the clinical protocols and informed consent/assent forms.
- Research-related subject costs.
- Basic and clinical research costs.
- Costs associated with the supply or availability of intervention(s).
- Other costs directly associated with planning and developing the Consortium.
- Travel costs of up to $3,600 per year to attend scientific/technical meetings.

Direct transfer of funds to a Government organization or agency is not allowed except under very limited circumstances and is subject to prior Grants Officer approval. **Funds provided**

through this award may not be used to support Government salaries. Details on exceptions to the prohibition of direct fund transfer to Government entities can be found in Section II.C.4.K (Federal Agency Financial Plan) of the General Application Instructions.

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to collaborate on applications to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements). Funds to intramural collaborators and other Federal agencies will be executed through the Military Interdepartmental Purchase Request or Funding Authorization Document process. Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The JPC-5/MOMRP expects to allot approximately $3.6M of the FY14 ASARP appropriations to fund approximately one ASARP Consortium Award application, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. Submission Information

Submission is a two-step process requiring both (1) a letter of intent submission through the electronic Biomedical Research Application Portal (eBRAP) https://eBRAP.org/ and (2) application submission through Grants.gov http://www.grants.gov/.

PIs must be registered in eBRAP in order to submit a letter of intent and receive notification of the status of an application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated to the organization in eBRAP (see *eBRAP User Guide* at

https://ebrap.org/eBRAP/public/UserGuide.pdf. Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

Note: Submission of either the letter of intent to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see Section IV.A., Rejection).

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov http://www.grants.gov/ basic search using the Funding Opportunity Number: W81XWH-14-ASARP-CA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/).

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
    - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Conflicts of Interest – Tab 3**
- FY14 ASARP Programmatic Review Panel members should not be involved in any pre-application or application. For questions related to FY14 ASARP Programmatic

Review Panel members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP at help@eBRAP.org or 301-682-5507.

- **Required Files – Tab 4**

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the overall Consortium vision and research strategy. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Submit Pre-Application – Tab 5**

  This tab must be completed for the pre-application to be accepted and processed.

C. Application Submission Content and Forms

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/).

Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification. The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in Section IV.A., Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP; if such changes are required, the entire application package must be submitted through Grants.gov as a "Changed/Corrected Application" with the Previous Grants.gov Tracking ID ***prior to the application submission deadline (which occurs earlier than the end of the application verification period).***

Grants.gov application package components: For the ASARP Consortium Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
2. **Attachments Form**
   - **Attachment 1: Project Narrative (35-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an

unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. ***The Project Narrative must include preliminary and/or published data that is relevant to ASUD and the proposed research project***.

- **Overall Strategic Research Plan:** Describe the Consortium aims and objectives. Include the scientific rationale behind the Consortium approach to achieve the aims and objectives. The plan should include a description of the types of studies that will be solicited and how these will contribute toward accelerating the delivery of effective treatments for ASUD. The plan should project the number, types, and scope of basic research projects and clinical studies the Consortium expects to execute during the performance period of the award. The strategic plan should outline a feasible timeline that aligns milestones and deliverables with the Consortium aims and objectives. It is expected that that within the first year of award, a solicitation will be released and at least 2 studies will be selected and initiated. Include a brief description of planned potential future studies. Note how the key components (core leadership and research projects) will be integrated to meet the overarching objectives of the Consortium and address the goals of the ASARP.
- **Consortium Expertise and Resources:** Describe the multidisciplinary expertise and the experience of the Management Core in support of ASUD research. Describe the expertise and previous experience of the Management Core PI, and other key personnel with respect to their role(s) in the Consortium. Include previous experience with financial and intellectual property management, and oversight of regulatory strategies of multi-institutional studies. Describe the available Consortium resources and previous experience with the establishment and management of multi-institutional collaborative relationships. Describe any experience working with military and Veteran populations and access to appropriate populations. Describe any plans to leverage existing clinical or translational programs and infrastructure for the proposed Consortium. Reference relevant publications and submit reprints or citations with the application supporting documentation.
- **Coordination of Consortium Components:** Outline the organizational structure of the proposed Consortium and identify key personnel. Describe the Management Core plan to oversee and coordinate all basic research and clinical trial sites as an integrated unit. Include a plan for the establishment and maintenance of core infrastructure that will effectively support Consortium activities and study sites. Outline a strategy for the identification, design, and prioritization of Consortium studies (including independent external peer review process and a process for determining site participation).
- **Study Project Management and Monitoring:** Describe the plans for real-time communication among all organizations participating in the Consortium, including complete and timely reporting of adverse events. Describe the Consortium Clinical Research Manager's experience with guiding clinical

protocols through the regulatory approval processes, coordinating participant accrual, and coordinating study activities across sites (if applicable). Outline procedures for quality assurance, quality control, safety, and study monitoring of multi-institutional studies.

- **Specimen Handling and Distribution:** Describe plans and methods for the collecting, handling, distribution, analysis, banking, and security of any specimens and/or imaging products generated from Consortium-sponsored studies (if applicable).
- **Clinical Protocol Development and Human Subjects' Protections:** Describe plans for coordinating the development of clinical protocols and associated clinical documents that address HRPO (and VA IRB if applicable) requirements. Outline a plan for the external peer review of all Consortium clinical protocols and the coordination of IRB submissions and approvals. Outline plans for developing procedures to ensure compliance with FDA regulations for investigational agents are considered when relevant.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.*
  - References Cited: List the references cited (including URLs if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
  - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
  - Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.

- Letters of Support for Use of Military and VA Populations or Resources (if applicable): Provide a letter(or letters, if applicable), signed by the appropriate approval authority for studies involving military Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.
- Letters of Collaboration: Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - Intellectual and Material Property Plan: Provide a plan for resolving intellectual and material property issues among participating organizations.
  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- Quad Chart: Complete the one-page Quad Chart Form (available for download in eBRAP) as instructed.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers. Clarity and completeness within the space limits of the technical abstract are highly important.
  - Background: Describe the general management and organizational structure of the Consortium. Outline the management and clinical expertise of Consortium personnel at the Management Core.
  - Objectives: Describe the Consortium's overall research goals and agenda.
  - Research Strategy: Briefly describe the Consortium research strategy during the performance period and the types of basic research and clinical studies that are anticipated to reach the goals.
  - Military Benefit: Briefly describe the relevance of the proposed Consortium to military Service Members, Veterans, their family members, and the general public. Include the likely contributions of this Consortium to advancing the field of ASUD research and to improving treatment outcomes, especially related to TBI and PTSD.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf."

  Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the advocate community, that are defined as individuals who have participated in or are the caregiver for those who have accessed treatment for ASUD and other health-related services.

  - Describe the objectives and rationale for the proposed Consortium in a manner that will be readily understood by readers without a background in science or medicine.
  - Describe the ultimate applicability of the basic and clinical research.
    - What types of patients will it help, and how will it help them? Include the current available statistics to the related injury/condition.
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected timeline it may take to achieve expected clinically relevant outcomes?
    - What are the likely contributions of this Consortium to advancing the field of ASUD research and to improving treatment outcomes, especially related to TBI and PTSD?
  - Briefly describe how the proposed Consortium will benefit Service Members, Veterans, their family members, and the general public.

- **Attachment 5: Statement of Work (SOW) (10-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

  The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Program Announcement and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the ASARP Consortium Award mechanism, use the SOW format example titled "SOW Generic Format." The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact and Benefit Statement (two-page limit): Upload as "Impact.pdf."**

  State explicitly how the proposed work, if successful, will have a significant impact on ***alcohol and substance abuse experienced by Service Members and Veterans especially related to PTSD and TBI.***

  - Describe the potential immediate and long-term effect on patient care and how the proposed work would impact the health care needs of Service Members and/or Veterans as well as their families, caregivers, and the general public.

- Describe how the proposed Consortium is responsive to the health care needs of military Service Members and Veterans with ASUD, especially as related to PTSD and TBI. Provide information about the incidence and/or prevalence of ASUD in military Service Members and/or Veterans, if appropriate and available.
- If active duty military and/or Veteran population(s) will be used in the proposed research, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of accessing the population. If a non-military population will be used for the proposed research, explain how the population simulates the targeted population (i.e., military Service Members or Veterans).

- **Attachment 7: Data Management Plan:** Upload as "DataPlan.pdf." Describe the overall approach to data collection, management, analysis, and security measures and how the data will be shared with the research community. Provide a data management plan that includes: (1) descriptions of the overall approach to establishing common data elements across the study sites, data collection and management, (2) a statistical plan that includes methods to monitor quality and consistency of data collection, and methods to measure outcomes, (3) a plan for real-time data transfer, and (4) data security measures. Refer to the General Application Instructions, Appendix 4, Section L for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 8: Animal Research Plan:** Upload as "AnimalResPlan.pdf." When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted to the USAMRMC Animal Care and Use Review Office for review and approval prior to initiation. Institutions using DoD funds to support the use of animals in research, product development, and testing must adhere to the Animal Welfare Regulations, the Guide for the Care and Use of Laboratory Animals, and other applicable Federal and DoD regulations which are described in DoD Instruction 3216.01, and Army Regulation 40-33, The Care and Use of Laboratory Animals in DOD Programs.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., for detailed information.
   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
   - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.
    - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.

6. **R & R Sub-award Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

D. Verification of Grants.gov Application in eBRAP

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. ***The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.***

E. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in application rejection.

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines. All applications must be submitted through Grants.gov. Applicant organizations and all sub-recipient organizations must have a Data Universal Numbering System number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP, JPC-5/MOMRP, and ASARP and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Process

1. **Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:**

   - **Overall Strategic Research Plan**
     - How the overall strategic plan (aims and objectives) and the types of studies (including size and scope) to be supported by the Consortium address the goals of the ASARP.
     - How the Consortium Structure and Management Core are organized to meet the goals and objectives laid out in the Strategic Plan.
     - How the strategic research plan achieves the goals of the Consortium.
     - How the key components (core leadership and research projects) are integrated to meet the overarching objectives of the Consortium and address the goals of the ASARP.
     - How the scientific rationale of the Consortium strategic research plan addresses the goals of the ASARP.
     - How the timeline aligns to the milestones, deliverables and objectives of the Consortium.

- How feasible is the plan to initiate at least two studies within the first year of the award (number, types and scope of basic research projects and/or clinical studies).

- **Consortium Expertise and Resources**
  - To what extent the expertise and experience of the proposed Management Core PI and key personnel are appropriate to manage and oversee the Consortium.
  - To what extent the levels of effort of key personnel are appropriate for successful conduct of the proposed work.
  - To what extent the Consortium has the experience to provide financial and intellectual property management, and oversight of regulatory strategies of multi-institutional research.
  - To what extent the Consortium plans to leverage existing clinical or translational programs and infrastructure.
  - The degree of experience the Consortia has in working with military and Veteran populations and access to appropriate populations.
  - Evidence of experience with establishment and management of multi-institutional collaborative relationships.
- **Coordination of Consortium Components**
  - To what extent the proposed overall organizational structure of the Consortium supports the strategic research plan.
  - How well the Management Core addresses a plan to oversee and coordinate all Consortium sites so they function as an integrated unit.
  - How well the plan for the establishment and maintenance of core facilities will effectively support Consortium activities.
  - To what extent the strategy for the identification, design, and prioritization of future Consortium studies (including independent external peer review and a process for determining site participation) is appropriate.
- **Study Project Management and Monitoring**
  - How the plans for real-time communication among all organizations participating in the Consortium, including complete and timely reporting of adverse events, are appropriate.
  - The extent of the named Consortium Clinical Research Manager's experience with guiding clinical protocols through the regulatory approval processes, coordinating participant accrual, and coordinating study activities across sites (if applicable) is appropriate.
  - How the outlined procedures for quality assurance, quality control, safety, and study monitoring are adequate for conducting multi-institutional studies.
- **Specimen Handling and Distribution**

- How the plans and methods for specimen and/or imaging collecting, handling, distribution, analysis, banking, and security are appropriate.

- **Data Management and Sharing**
  - The degree to which the overall approach to data collection, management, analysis, security measures, and sharing with the research community is appropriate.
  - How the application of methods to monitor quality and consistency of data collection (to include use of CDEs across the studies) and methods to measure outcomes in previous trials conducted have been demonstrated by the PI and key personnel.
  - How the plan for real-time data transfer is adequate for supporting the Consortium-associated activities.
  - The degree to which plans for the publication and other dissemination of data are appropriate.

- **Clinical Protocol Development and Human Subjects' Protections**
  - The degree to which plans for the proposed clinical protocols and associated clinical documents are appropriate.
  - To what extent the plans for addressing human subjects' protection requirements as described by HRPO, VA (as applicable), and coordinating IRB submissions and approvals at participating sites are appropriate.
  - To what extent the plans for developing procedures to ensure compliance with FDA regulations for investigational agents (when relevant) are appropriate.
- **Impact and Benefit**
  - How the proposed Consortium is responsive to the health care needs of military Service Members and Veterans with ASUD, especially as related to PTSD and TBI.
  - Potential for the proposed Consortium to contribute significantly to ASUD research and accelerate the translation of promising ASUD treatments into clinical application.
  - How the proposed work would impact healthcare for Service Members and/or Veterans as well as their families, caregivers, and the general public

In addition, the following unscored criteria will also contribute to the overall evaluation of the application.

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influence the review.

2. **Programmatic Review: To make funding recommendations, the following equally considered criteria are used by programmatic reviewers:**

   a. Ratings and evaluations of the peer reviewers

   b. Relevance to the mission of the DHP, JPC-5/MOMRP and FY14 ASARP, as evidenced by the following:

   - Adherence to the intent of the award mechanism
   - Program portfolio balance and composition
   - Military and programmatic relevance
   - Relative impact
   - Transition potential

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.

Documents not requested will be removed.

Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in Section IV.A., Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- A FY14 ASARP Programmatic Review member is named as being involved in the research proposed or is found to have assisted in the application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY14 ASARP Programmatic Review members can be found at http://cdmrp.army.mil/asarp/panels/panels14.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Total costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Participation of any employee/contractor of CDMRP in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

D. Reporting

Refer to the General Application Instructions, Appendix 4, Section J, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required. Written progress reports and oral briefings will be requested.

E. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

B. Grants.gov Contact Center

Questions related to application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Layman Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Benefit Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Data Management Plan: Upload as Attachment 7 with file name "DataPlan.pdf"	
	Animal Research Plan: Upload as Attachment 8 with file name "AnimalResPlan.pdf."	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	